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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,436	03/21/2006	Robert A. Macina	DEX0477US.NP	6995
32800 75	90 09/18/2006		EXAM	INER
LICATA & TY			ZHOU, S	SHUBO
66 E. MAIN ST MARLTON, N			ART UNIT	PAPER NUMBER
·			1631	
			DATE MAILED: 09/18/2006	6

Please find below and/or attached an Office communication concerning this application or proceeding.

		Apı	plication No.	Applicant(s)	
	055 4 4 0	10	/553,436	MACINA ET AL.	
	Office Action Summary	Exa	aminer	Art Unit	
			ubo (Joe) Zhou	1631	
Period fo	The MAILING DATE of this commun or Reply	nication appears	on the cover sheet with the	ne correspondence a	ddress
WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE NOTES IN 1997. THE NOTES IN 1997 IN 19	MAILING DATE (s of 37 CFR 1.136(a). munication. tatutory period will app y will, by statute, cause	OF THIS COMMUNICAT In no event, however, may a reply by Iy and will expire SIX (6) MONTHS the application to become ABAND	ION. se timely filed from the mailing date of this of DNED (35 U.S.C. § 133).	
Status					
1) 又	Responsive to communication(s) file	ed on 14 July 20	006.		
2a)□	•	2b)⊠ This action			
3)□	Since this application is in condition	for allowance e	except for formal matters,	prosecution as to th	e merits is
,	closed in accordance with the pract		•	·	
Disposit	ion of Claims				
4)🖂	Claim(s) 1-18 is/are pending in the	application.			
. –	4a) Of the above claim(s) 7,11-15 au	nd 17 is/are with	drawn from consideration	า.	
5)□	Claim(s) is/are allowed.				
6)⊠	Claim(s) <u>1-6,8-10,16 and 18</u> is/are r	ejected.			
7)	Claim(s) is/are objected to.				
8)[Claim(s) are subject to restrict	ction and/or elec	ction requirement.		
Applicati	ion Papers				
9)⊠	The specification is objected to by th	ie Examiner.			
10)⊠	The drawing(s) filed on 11 October 2	2005 is/are: a)[☐ accepted or b)⊠ object	ted to by the Examir	ner.
	Applicant may not request that any obje	ction to the drawi	ng(s) be held in abeyance.	See 37 CFR 1.85(a).	
	Replacement drawing sheet(s) including	g the correction is	required if the drawing(s) is	objected to. See 37 C	FR 1.121(d).
11)	The oath or declaration is objected to	o by the Examin	er. Note the attached Off	fice Action or form P	TO-152.
Priority u	ınder 35 U.S.C. § 119				
·—	Acknowledgment is made of a claim ☐ All b)☐ Some * c)☐ None of:	for foreign prior	rity under 35 U.S.C. § 119	∂(a)-(d) or (f).	
	1. Certified copies of the priority	documents hav	e been received.		
	2. Certified copies of the priority		* *		
	3. Copies of the certified copies	• •		eived in this National	l Stage
	application from the Internation	•	• • •		
* 5	See the attached detailed Office action	on for a list of the	e certified copies not rece	eived.	
Attachmen	• •				
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (F	2TO-948)	4) Interview Summ Paper No(s)/Ma		
3) 🛛 Infor	mation Disclosure Statement(s) (PTO/SB/08) or No(s)/Mail Date 10/11/05.8/29/06,9/7/06.		5) ☐ Notice of Inform 6) ☑ Other: <u>see conti</u>	al Patent Application	

Continuation Sheet (PTOL-326)

Application No.

Continuation of Attachments 6):

- 1. Sequence alignment between SEQ ID NO:36 and M15041
- 2. Sequence alignment between SEQ ID NO:36 and SEQ ID NO:52

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DETAILED ACTION

Election/Amendments

1. Applicants' election, with traverse, of Group I, drawn to polynucleotides (claims 1-6, 8-10, 16 in part and 18 in part) and SEQ ID NO:36 in the response filed 7/14/06 is acknowledged. The traversal is on the ground(s) that there would be no serious search burden to examine all the groups together, and that requirement of election of a single sequence is improper. This is not found persuasive because, firstly, reasons that there would be a serious search burden if groups I-IV were examined were set forth in the previous Office action on pages 3-7. Applicants do not argue against those reasons. With regard to the single sequence election requirement, as also set forth in the previous Office action on page 7, that "the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement."

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1-18 are currently pending, but only claims 1-6, 8-10, 16 in part and 18 in part are under examination. Claims 16 and 18 are examined to the extent of the elected invention, i.e. nucleic acids.

Claims 7, 11-15 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/14/06.

The preliminary amendment to the specification filed on 10/11/05 is also acknowledged and entered.

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Sequence Rules Compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR, 1.821(a)(1) and (a)(2). Such sequences are present in Figures 1-3 and 5. However, this application fails to comply with the requirements of 37 CFR, 1.821 through 1.825 because there sequences are not followed by a sequence identifier ("SEQ ID NO:X"). Applicants are reminded that it is required that SEQ ID Nos be amended into the specification at each sequence, and that when a sequence is presented in a drawing regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings.

Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to comply with these requirements may result in ABANDONMENT of the application under 37 CFR 1.821(g).

Information Disclosure Statement

3. The Information Disclosure Statements filed 10/11/05, 8/29/06, and 9/7/06 have been entered and references disclosed therein have been considered. Initialed copies of the form PTO-1449 are enclosed with this action.

Drawings

4. The drawings filed 10/11/05 are objected to because of the following: 37 CFR 1.84(u) states:

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Partial views intended to form one complete view, on one or several sheets, must be identified by the same number followed by a capital letter. View numbers must be preceded by the abbreviation "Fig."

In the instant application, sheets 1-9 are partial views of a sequence alignment, sheets 10-12 are partial views of a sequence alignment, sheets 13-18 are partial views of a sequence alignment, and sheets 20-21 are partial views of another sequence alignment. These partial views are not identified as required by 37 CFR 1.84 as set forth above. It is suggested that the partial views be numbered, e.g. as Fig. 1A, Fig. 1B, etc.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The specification is objected to because of the following:

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The title of the invention is not descriptive. The elected invention is drawn to an isolated nucleic acid. The current title, however, is directed to compositions, splice variants and methods relating to cancer specific genes and proteins. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

It appears that trademark is used in this application, such as PLATINOL on page 24. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to also because it contains an embedded hyperlink and/or other form or browser-executable code. Such code is present in the specification at page 24 and elsewhere. Applicants are required to delete all the embedded hyperlinks and/or other forms of browser-executable code. See MPEP ' 608.01.

There are many tables disclosed in the specification, e.g. the tables on pages 37, 153-157, 158-249. Not all tables are numbered, and confusingly, the table that is labeled as Table 1 is not the first table disclosed in the specification. See page 255.

It seems that the word "form" before the phrase "the same patient" on page 394, line 6, should be "from."

Appropriate correction is required.

Claim Rejections-35 USC § 101 and § 112

6. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-6, 8-10, 16 and 18 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

Claims 1-6, 8-10, 16 and 18 are drawn to isolated nucleic acid molecules comprising the sequence of SEQ ID NO:36 or a sequence that encodes the amino acid sequence of SEQ ID NO:194, which is encoded by SEQ ID NO:36.

The specification discloses that the sequence of SEQ ID NO:36 is also referred to as DEX0477_020.nt.2 (see page 154), which is, in turn, referred to also as Cln224v1 (see page 392).

The claimed nucleic acid molecule is not supported by a specific, substantial and credible asserted utility.

The specification asserts that Cln224v1 is "useful as a diagnostic marker and/or therapeutic target for cancers of the gastrointestinal tract." See page 394, lines 7-10.

Consideration of the expression of Cln224v1 in different cancer tissues disclosed in the specification reveals that this is not a substantial and credible utility.

The specification on pages 394-395 discloses that 40% of the colon cancer samples have an over-expression of Cln224v1 as compared to normal tissues or normal adjacent tissues, but also 44% of lung cancer samples and 22% of breast cancer tissues have an over-expression of Cln224v1 as compared to normal tissues or normal adjacent tissues. Furthermore, 50% of the colon cancer samples have a down-expression of Cln224v1 as compared to normal tissues or

normal adjacent tissues, and 33 % of lung cancer samples have a down-expression of Cln224v1 as compared to normal tissues or normal adjacent tissues. No statistical analyses are given to indicate any statistical significance of the data. For a nucleic acid molecules that is over-expressed in some colon cancer samples, in some lung cancer samples and some breast cancer samples, and at the same time, it is also down-expressed in certain colon cancer samples and in certain lung cancer samples, one skilled in the art would have reasonable doubt that it would be "useful as a diagnostic marker and/or therapeutic target for cancers of the gastrointestinal tract." Further research is apparently needed to determine whether such a molecule can be used as such a marker. The apparent need for such research indicates that the nucleic acid molecule is not disclosed as to a currently available or substantial utility.

Recently, in *In re Fisher*, a case analogous to the present application, the court, following an analysis of Nelson, 626 F.2d at 856, with regard to substantial utility, states that "it thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research." *In re Fisher*, 76 USPQ2d 1225 1230 (CAFC 2005). In the instant case, the application does not show that the claimed polynucleotide is useful to the public as disclosed in its current form, but that it may prove useful at some future date after further research.

Further, neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid comprising SEQ ID NO:36 or the polypeptide encoded thereby such that another non-asserted utility would be well established for the nucleic acid or its encoded polypeptide.

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8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-6, 8-10, 16 and 18 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention lacks a patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

10. Claims 16 and 18 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art. The factors are analyzed for the instant case as follows:

In the instant case, the amount of experimentation required by the skilled artisan in order to practice of using the claimed nucleic acid for detecting a risk or presence of cancer in a patient

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or as a vaccine would require an unpredictable amount of experimentation for the following reasons:

The claims are drawn to a kit comprising the claimed nucleic acid for detecting a risk or presence of cancer in a patient (claim 16) or a vaccine comprising the claimed nucleic acid. As set forth above, the specification on pages 394-395 discloses that 40% of the colon cancer samples have an over-expression of Cln224v1 as compared to normal tissues or normal adjacent tissues, but also 44% of lung cancer samples and 22% of breast cancer tissues have an overexpression of Cln224v1 as compared to normal tissues or normal adjacent tissues. Furthermore, 50% of the colon cancer samples have a down-expression of Cln224v1 as compared to normal tissues or normal adjacent tissues, and 33 % of lung cancer samples have a down-expression of Cln224v1 as compared to normal tissues or normal adjacent tissues. No statistical analyses are given to indicate any statistical significance of the data. For a nucleic acid molecules that is overexpressed in some colon cancer samples, in some lung cancer samples and some breast cancer samples, and at the same time, it is also down-expressed in certain colon cancer samples and in certain lung cancer samples, one skilled in the art would not know how to use it to detect the risk or presence of a cancer in a patient or use it as a vaccine. The specification does not provide guidance, nor does it provide any working example, as to how to use such a nucleic acid molecule to detect the risk or presence of a cancer in a patient or use it as a vaccine.

The nature of the invention, i.e. a kit comprising a nucleic acid molecule for use to detect the risk or presence of a cancer in a patient or as a vaccine, is complex. The prior art does not teach or fairly suggest such a kit or vaccine. The skilled practitioner would first turn to the instant specification for guidance in practice of using the kit comprising the nucleic acid molecule comprising the sequence of SEQ ID NO:36 to detect the risk or presence of a cancer in a patient or use it as a vaccine. However, the specification does not provide sufficient guidance

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or working example of practicing the invention. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art does not teach such a kit or vaccine. Finally, said practitioner would have to turn to trial and error experimentation for practicing using the claimed nucleic acid for detecting the risk or presence of a cancer in a patient or use it as a vaccine without adequate guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

11. Claims 1-6, 8-10, 16 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are rejected mostly for the same reasons as those set forth in the "Revised Interim Written Description Guidelines Training Material" for similar claim limitations. The training material is available on the US PTO's website:

http://www.uspto.gov/web/patents/guides.htm, and its relevant sections are attached to this Office action. Please especially see Examples 6, 9, 10, 11, and 13.

The claims are drawn to a genus of nucleic acid molecules including any nucleic acid molecule that selectively hybridizes to the nucleic acid of SEQ ID NO:36 or any nucleic acid molecules that encode the polypeptide of SEQ ID NO:194, which is also encoded by SEQ ID NO:36. Since the claims do not specify any stringency conditions for the hybridizations, and do not contain functional limitations, the claims are broad and read on virtually any nucleic acids

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because almost any polynucleotides can hybridize to the a molecule comprising SEQ ID NO:36 under certain hybridization conditions and the hybridization is selective because it would not hybridize to other molecules such as proteins as the specification does not explicitly defines the metes and bounds of the phrase "selectively hybridize." Clearly, there is substantial variability among the species encompassed by the scope of the claims because the genus encompasses a variety of species with different structures and distinct functions.

A description of a genus may be achieved by means of a recitation of a representative number of species, falling within the scope of the genus, or by means of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In the instant case, the specification discloses only a species: the nucleotide sequence of SEQ ID NO:36, but, as set forth above, the lack of stringency of hybridization conditions and the lack of functional limitation would be expected to yield structurally unrelated nucleic acid molecules. Thus, the single disclosed species is not representative of the genus because there is no structural attribute or feature that is common to the members of the genus.

Therefore, one skilled in the relevant art would have reasonable doubt that the inventor(s), at the time the application was filed, had possession of the claimed invention.

12. The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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13. Claims 2-6, 8-10, 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-6, 8-10, 16 and 18 all recite the phrase "the nucleic acid molecule according to claim 1, wherein the nucleic acid molecule." Claim 1 refers to multiple different nucleic acid molecules: the nucleic acid molecule of (a), of (b), of (c), of (d), and the nucleic acid molecule comprising the molecule of (a), (b), (c), or (d). Thus, it is not clear as to what nucleic acid molecule is referred to in claims 2-6, 8-10, 16 and 18 by "the nucleic acid molecule according to claim 1."

Clarification of the metes and bounds of the claims is requested.

Claim Rejections-35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 15. Claims 1-2, 4-6, 8-10, and 16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Oikawa et al. (Biochemical and Biophysical Research Communications, Vol. 142, pages 511-518).

The claims are drawn to any nucleic acid molecules that selectively hybridize to the nucleic acid of SEQ ID NO:36.

Oikawa et al. disclose a nucleic acid molecule, referred to as CEA, comprising a sequence that is about 80% identical to the sequence of SEQ ID NO:36. See the attached sequence alignment between SEQ ID NO:36 and the sequence of GenBank accession number

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M15041, which is the same sequence as that disclosed by Oikawa et al. See the text portion of the sequence alignment. Given that the two sequences share such a relatively high sequence identity and that the claims do not specify any hybridization conditions, it would be readily apparent to one skilled in the art that the two sequences would hybridize to each under certain, e.g. low to medium conditions, and the hybridization would be selective because they would not hybridize to other molecules such as proteins.

As to claim 2, Oikawa et al. disclose a cDNA molecule comprising the sequence.

As to claims 4-6, given that Oikawa et al. disclose that the cDNA was obtained from RNA of human colon tissues (see pages 512-513), it is apparent that Oikawa et al. also disclose an RNA molecule that hybridizes with the nucleic acid comprising SEQ ID NO:36, and the nucleic acid molecules are from human, which is a mammal.

As to claims 8-9, Oikawa et al. disclose that the cDNA is in the vector lambda gt11 and in E. coli cells.

As to claim 10, Oikawa et al. disclose that the cDNA clone from the cDNA library is done by immunoscreening assays with a rabbit anti-CEA antibody. Given that it would be well known that the lambda gt11 vector is an expression vector comprising control sequences allowing the expression and translation of the insert sequence, and that the immunoscreening assay is an assay wherein the insert is allowed to be expressed and polypeptide is produced in the host cells before the binding assay with the antibody, it is apparent that Oikawa et al. disclose a method for producing the polypeptide encoded by CEA.

As to claim 16, given that the CEA cDNA is isolated by Oikawa et al. in a laboratory, it must have been contained in a container. Such a container having therein the cDNA is interpreted as being a kit.

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16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (f) he did not himself invent the subject matter sought to be patented.
- 17. Claims 1-6, 8-10, 16 and 18 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

For the reasons discussed below in the section of double patenting rejection, it is apparent that copending Application No. 10/558861 contains claimed subject matter in claims that is not patentably distinct from instant claims 1-6, 8-10, 16 and 18. Because the inventive entity of copending Application 10/558861 is different from the instant application, a rejection is appropriate under 35 U.S.C. 102(f). This rejection could be overcome by amendment of the appropriate claims so that the claims are patentably distinct, or by filing a declaration stating the inventive entity for the commonly claimed subject matter is identical.

Provisional Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-6, 8-10, 16 and 18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8-10, 16 and 18 of US copending Application No. 10/558861.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6, 8-10, 16 and 18 of the instant application are drawn to nucleic acid molecules comprising the sequence of SEQ ID NO:36 or any nucleic acid that encodes the polypeptide of SEQ ID N):194, which is encoded by SEQ ID NO:36, or any nucleic acids that hybridize selectively with any of the above.

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At least for one embodiment, 1-6, 8-10, 16 and 18 of US copending Application No. 10/558861 are drawn to nucleic acid molecules comprising the sequence of SEQ ID NO:52 or any nucleic acid that hybridizes selectively with the sequence of SEQ ID NO:52. Sequence comparison performed by the Office shows that the sequence of SEQ ID NO:52 of the copending application is identical to the SEQ ID NO:36 of the instant application. Thus, claims 1-6, 8-10, 16 and 18 of the instant application are anticipated by claims 1-6, 8-10, 16 and 18 of the copending US application, respectively.

Conclusion

- 20. No claim is allowed.
- 21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of

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the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.

Patent Examiner

CEA cDNA Binding d Cancer/an Human can Human CEA

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US-10-558-861-52
; Sequence 52, Application US/10558861
; Sequence 52, Application US/10558861
; GENERAL INFORMATION:
; APPLICANT: diaDexus, inc.
; APPLICANT: Macina, Roberto
; APPLICANT: Turner, Leah
; APPLICANT: Turner, Leah
; TITLE OF INVEXTION: Compositions, Splice Variants and Methods Relating to Ovarian Spe
; TITLE OF INVEXTION: Nucleic Acids and Proteins
; FILE REFERENCE: DEX-0487
; CURRENT PLING DATE: 2005-11-30
; PRIOR PLING DATE: 2005-11-30
; PRIOR PLING DATE: 2003-05-30
; NUMBER OF SEQ ID NOS: 245
; SSOFTWARE: PatentIn version 3.1
; SEQ ID NO 52
; LENGTH: 3373 3301 GGCATGAACCCCGGGAGGCAGGGCTTGCAGTGAGCCAAGATCATGCCGCTGCACTCCAGAGTC 3968 180 180 240 300 360 AGCATCTTTTTGGCTACAGCTGGTACAAGGTGAAAGAGTGGCAAGCGTCAAGTTA 360 420 420 480 540 TATACCCGGAGCTGCCCAAGCCCTCCAACAACAACTCCCAAACCGTGGAGGACA 600 9 CCATGGAGTCTCCCTCGCCCTCCCCACAGATGGTGCATCCCCTGGCAGAGGCTCCTGC TCACAGCCTCACTTCTAGAACCCGCCCACCACTGCCAAGCTCACTATTGAAT CCACGCCGTTCAATGTCGCAGAGGGGAAGGGGTGCTTCTACTTGTCCACAATCTGCCCC 301 AGCATCTITITGGCTACAGCTGGTACAAGGTGAAAGAGTGGATGGCAACGGTCAAATTA 361 TAGGATATGTAATAGGAACTCAACAAGGTACCCCAGGGCCCGCATACAGTGGTCGAGAGA TAATATACCCCAATGCATCCCTGCTGATCCAGAACATCCAGAATGACACAGGATTCT **ACACCCTACACGTCATAAAGTCAGATCTTGTGAATGAAGAAGCAACTGGCCAGTTCCGGG** Gaps ö DB 51; Length 3373; Indels Query Match 100.0%; Score 3373; DB 51; Best Local Similarity 100.0%; Pred. No. 0; Matches 3373; Conservative 0; Mismatches 0; DECHACATART 3373 3361 TGGGAGACAAAGT 3373 ; TYPE: DNA ; ORGANISM: Homo sapien US-10-558-861-52 421 421 541 541 61 61 121 121 181 181 241 241 301 481 ò g 유 셤 셤 ò 셤 ò 셤 8 셤 ठ g ઠે 셤 ò ð ò ઠે ઠે

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                                                                           Original source text: Human malignant colon tissue, cDNA to mRNA, clones pCEA[55-2,80-11]. Clean copy of sequence [1] kindly provided by S.Oikawa (25-MAR-1987).
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   TCTAACCTTCTGGAACCCGCCCACCACCCAAGCTCACTATTGAATCCACGCCGTTCAA
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            from cDNA sequence
Biochem. Biophys. Res. Commun. 142 (2), 511-518 (1987)
3814146
                                                                                                                                                                                                                                                                                                                                                                          /note="carcinoembryonic antigen precursor"
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|protein_id="AaA51963.1"
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/note="truncated Alu repeat"
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79.5%; Score 2681; D

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/db_xref="taxon:9606"
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V	RESULT 4 RO1630 DOCUS DEFANTION ACCESSION VERYWORDS SOURCE ORGANISM TITLE JOURNAL COMMENT	E01630 ROLORA encoding human carcinoembryonic antigen. E01630.1 GI:2169883 E01630.1 GI:2169883 JP 198817734-A/1. Homos capiens thuman) Homos capiens thuman Homos capiens thuman Homos capiens thuman Notwas, and Nakazato, H. Homos capiens thuman Homos capiens thuman
		FT CDS / 12929 FT CDS / product='human carcinoembryonic autigen' FT signal peptide of human FT cacinoembryonic antigen' FT mat_peptide 612094 FT mat_peptide 612094 FT carcinoembryonic antigen'